K001581

MAR 2 0 2001

510 (K) Summary of Safety and Effectiveness

Submitter: Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, IN 46581-0587

Contact Person: Carol Lauster

Product Code: MAI and HWC

Device Name: LactoSorb® 5.0 mm Washer

Indications For Use
The LactoSorb® 5.0 mm Washer is used in conjunction with the Biomet Bone Screw (K964970) for ankle fractures, metatarsal fusions, and metatarsal osteotomies (Hallux Valgus) in the presence of appropriate protection or immobilization (e.g. casting, bracing, external fixator etc.).

Device Description
The LactoSorb® Washer is designed to accommodate a 5.0 mm Biomet (LactoSorb®) Bone Screw. The washer is 15 mm in diameter and is comprised of the exact same LactoSorb® material as the screw.

The Biomet (LactoSorb®) Bone Screws consists of partially threaded (malleolar) and fully threaded (cortical) screws. The malleolar screw lengths range from 15-35 mm, in 5 mm increments, and are solid or cannulated. The cortical screw lengths range from 35-70 mm, in 5 mm increments and are also solid and cannulated. The screw can be used with or without the washer.

Summary of Testing
In vitro pullout testing comparing the 5.0mm screw/washer construct to the predicate screws was performed. The addition of the washer did not affect the pullout strength of the screw/washer combination through the eight weeks time period *in vitro*.

Predicates Devices
Biomet Bone Screw: K964970
Biofix SR-PGA Screws: K920188

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ms. Carol Lauster
Regulatory Specialist
Biomet, Inc.
56 East Bell Drive
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K001581
Trade Name: Lactosorb 5.0 mm Washer/Screw System
Regulatory Class: II
Product Code: HWC, MAI
Dated: January 4, 2001
Received: January 5, 2001

Dear Ms. Lauster:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K001581

DEVICE NAME: LactoSorb® 5.0 mm Washer

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(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K001581